UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 23 1993

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Triphenyltin Hydroxide (TPTH). Case No. 0099. Registrants' Response to Reregistration Standard Update of 3/92. CBRS No. 12109. DP Barcodes: D192579.

FROM: Leung Cheng, Chemist
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TO: Walt Waldrop, Product Manager 71
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Attached is a review of residue chemistry data, primarily method validation data, for triphenyltin hydroxide submitted by the registrant in response to the TPTH Reregistration Standard Update dated 3/18/92. This information was reviewed by Acurex Corporation under the supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies.

The registrant is still deficient on the following topics of residue chemistry data requirements: validation data for processed commodities of potatoes and sugar beets, an enforcement method for plant commodities, residue and enforcement methodology in animal commodities, sample chromatograms to support the storage stability data, residue data in sugar beet tops, and animal feeding studies. Enforcement methods must not require the use of an internal standard.

A tentative chemical status sheet is attached.

Attachment: Acurex review of residue chemistry data
cc(without Attachment):RF
cc(with Attachment):Circ, SF, Reg Std File, Cheng, Acurex
RDI:ARRathman:11/10/93:MMetzger:11/22/93:EZager:11/22/93
H7509C:CBRS:LCheng:CM#2:RM804/810D:11/3/93:03:A\TPTH\ACUREX.2

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TRIPHENYLTIN HYDROXIDE
(Chemical Code 083601)
(CBRS No. 12109; DP Barcode D192579)

TASK 3

Registrant's Response to Residue Chemistry Data Requirements

September 10, 1993

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

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TRIPHENYLTIN HYDROXIDE

(Chemical Code 083601)

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REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY REQUIREMENTS

Task 3

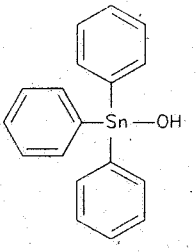
BACKGROUND

The Triphenyltin Hydroxide (TPTH) Guidance Document (9/84) required data on analytical methods, storage stability, and magnitude of the residue. In response, the registrants submitted data pertaining to analytical methods and residue data on potatoes and sugar beets that were reviewed in the TPTH Reregistration Standard Update, dated 3/18/92. The Update cited a number of deficiencies in the analytical methodology and required additional data on the analytical methods, storage stability of residues, and residue data for potatoes and sugar beets. In the current submission (1990; MRID 42806101), Atochem North America, Inc. (also on behalf of Griffin and Hoechst-Celanese) has responded to the deficiencies cited in the TPTH Update. These responses are reviewed here to determine their adequacy in fulfilling outstanding residue chemistry data requirements. The Conclusions and Recommendations stated herein pertain only to data requirements for residue analytical methods, storage stability data, and residues data for potato and sugar beet RACs and processed commodities.

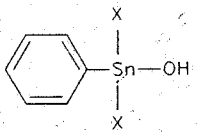
The nature of the residue in plants and animals is adequately understood. The residues of concern in plants and animals consist of TPTH per se and its monophenyltin (MPTH) and diphenyltin (DPTH) hydroxide and oxide metabolites. Tolerances are currently established for residues of TPTH per se in or on raw agricultural commodities (40 CFR §180.236). However, the 1984 Guidance Document and the Update have recommended that tolerances be revised to also include the monophenyltin and diphenyltin hydroxides and oxides.

Colorimetric methods are available in PAM, Vol. II for determining residues of TPTH per se in or on plant commodities, and are listed as Methods I-IV. However, these methods would not be adequate for enforcing revised tolerances including DPTH and MPTH. The 1984 Guidance Document required development of methodology capable of quantifying TPTH and the two degradates either collectively or separately in plant and animal commodities. In addition, the method for animal commodities should include a base hydrolysis step to release residues from conjugates.

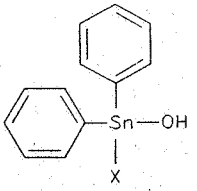
As there are no Codex MRLs for residues of TPTH, there is no question with respect to Codex/U.S. tolerance compatibility.



Triphenyltin hydroxide (TPTH)



Monophenyltin hydroxide (MPTH)



Diphenyltin hydroxide (DPTH)

CONCLUSIONS/RECOMMENDATIONS

1a. Recoveries from fortified samples using the Graphite Furnace Atomic Absorption Spectroscopy (GFAAS) method and the GC/flame photometric detection (FPD) method varied widely depending on the sample matrix and the phenyltin compound used for the fortification. The registrant has submitted acceptable information discussing the method for determining the theoretical MDLs (method detection limit) for the GFAAS method and the GC/FPD method. The submitted validation data indicate that the GFAAS method is adequate for collecting data on total organotin (ΣOT) in or on potato and sugar beet RACs, but not for collecting residue data from potato and sugar beet processed commodities. Validation data and concurrent method recovery data for the GC/FPD method used to determine the individual phenyltin compounds indicated that this method is adequate for collecting residue data from potato and sugar beet RACs, but not for processed commodities. Validation data at levels of 0.05 ppm for potato granules and chips and 0.1 ppm for refined sugar and molasses (sugar beet) are needed.

The inclusion of an internal standard in an enforcement method to account for derivatization inefficiencies is not acceptable. According to the Residue Chemistry Guidelines, the registrant must develop an enforcement method that does not require this type of an internal standard for quantifying residues.

1b. The registrant must submit methodology for the enforcement of tolerances for residues of TPTH, DPTH, and MPTH in meat, milk, poultry, and eggs. The method(s) should include a base hydrolysis step to release conjugated residues. Alternatively, the registrant must provide data indicating that base hydrolysis is

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unnecessary for adequate recovery of the total toxic residue. A complete description of the method(s) and appropriate validation data must be submitted.

1c. The proposed tolerance enforcement methodology must undergo successful confirmatory trials conducted by an independent laboratory. For specific requirements, refer to PR Notice 88-5, Tolerance Enforcement Methods-Independent Laboratory Confirmation by Petitioner. In addition, representative samples from plant and animal metabolism studies must be analyzed using proposed enforcement methodology in order to ascertain that these methods are capable of recovering all residues of concern. If analysis of samples from previously accepted metabolism studies is impractical, the registrant must provide data from other sources to demonstrate adequate recovery of the total toxic residue.

2. Storage stability data for residues of TPTH in potato and sugar beet RACs and processed commodities have been reviewed (1992, MRID 42564801; CBRS No. 11004, L. Cheng, 3/11/93). CBRS deferred conclusions pending submission of representative chromatograms for the calibration curves, standards, and treated and untreated samples. Storage stability data for TPTH residues in sugar beet tops and in animal commodities remain outstanding.

3a. Residue data for sugar beet tops remain outstanding. The registrant must also revise its product labels to prohibit the use of TPTH on sugar beets grown in CA or submit data from CA depicting TPTH residues in or on sugar beet tops and roots treated with TPTH at the maximum label rates.

3b. Carrot and peanut uses have been deleted from TPTH product labels; therefore, no additional data are required for these crops.

3c. Magnitude of the residue data reviewed in the TPTH Update were expressed in terms of Sn. In order to properly assess the tolerances for residues of TPTH in or on potatoes and sugar beets, all residue data used to support the established tolerances must be converted to TPTH equivalents.

Note to SRRD: The tolerance expression for TPTH residues in or on raw agricultural commodities should be revised to read "for the combined residues of the fungicide triphenyltin hydroxide (TPTH) and its monophenyltin (MPTH) and diphenyltin (DPTH) hydroxide and oxide metabolites, expressed in terms of parent TPTH." In addition, the registrant is no longer supporting the use of TPTH on carrots or peanuts; therefore, TPTH tolerances for carrots, peanuts, and peanut hulls should be deleted from 40 CFR §180.236.

DETAILED CONSIDERATIONS

Deficiencies cited in the 3/92 TPTH Update pertaining to analytical methodology, storage stability data, and magnitude of the residue data are listed below along with Atochem's responses (1992; MRID 42806101) and CBRS' conclusions.

CBRS Deficiencies #1 and #2

The registrant must provide additional data to allow judgement as to the adequacy of their GFAAS/GLC methodology used to collect data on potatoes, sugar beets, and processed commodities. Raw data are needed from the analyses used to derive the theoretical method limits of detection reported for DPTH and MPTH, and the registrant must explain their rationale for determining the method limits of detection in this manner.

The registrant must also provide data demonstrating that each phenyltin species can be adequately recovered from each regulated commodity fortified at the stated limit of detection and tolerance level.

Registrant Response

The registrant stated that the procedures used for determining the method detection limits (MDL) were derived from the Federal Register, Vol. 49, No. 209, 10/84, pp. 198-199, and were determined using the following formula: MDL = t_7 x standard deviation where t_7 is presumably the Student t test. The registrant provided tables containing the raw data from the analyses used to determine the MDLs for the total organotin (ΣOT) GFAAS method and the phenyltin GC/FPD method for sugar beets and potatoes.

The registrant also provided summary tables from the original submissions containing method validation data for the GFAAS and GC/FPD methods for potato and sugar beet matrices.

CBRS Conclusion

The registrant has adequately addressed the deficiency regarding how the MDL's were determined. The registrant has not provided adequate validation data to support the reported MDL's. Based on the validation data provided by the registrant and summarized in Table 1, the lowest levels validated for the GFAAS method for determining ΣOT in or on potatoes are 0.031, 0.015, and 0.015 ppm for MPTH, DPTH, and TPTH, respectively. The lowest levels validated for the GFAAS method for determining ΣOT in or on sugar beets are 0.015, 0.06, and 0.06 ppm for MPTH, DPTH, and TPTH, respectively. Because tolerances for TPTH residues are currently 0.05 and 0.1 ppm for potatoes and sugar beets, respectively, the GFAAS method is adequate for data collection of ΣOT residues in these RACs.

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Based on the validation data summarized in Table 2 for the GC/FPD method for determining the individual phenyltin compounds, the lowest levels validated for potatoes are 0.04, 0.37, and 0.031 ppm for MPTH, DPTH, and TPTH, respectively. The lowest levels validated for the same method with sugar beets are 0.38, 0.07, and 0.015 ppm for MPTH, DPTH, and TPTH, respectively. The lowest levels validated for the combined TPTH residues are within the current tolerances for TPTH residues in or on potatoes and sugar beets. The GLC/FPD method is adequate for data collection of TPTH, monophenyltin and diphenyltin compounds in potatoes and sugar beets.

The GFAAS and GC/FPD validation data show that there is a high degree of variability in the method recoveries among the specific analytes and the matrix analyzed. We are unable to determine the adequacy of either the GFAAS or the GC/FPD method for sugar beet processed commodities since individual recovery levels were not provided. Validation data for the processed potato commodities for either method are inadequate since the bulk of the fortification levels were conducted at 0.2 ppm, which is outside the tolerance level. Validation data at levels of 0.05 ppm for potato granules and chips and 0.1 ppm for refined sugar and molasses are needed.

Validation data from a reverse phase HPLC discussed in earlier reviews (L. Cheng, 4/25/90, no CBRS No.) showed 79% to 127% recoveries when potatoes and sugar beets were fortified at 0.01 ppm TPTH.

Table 1. Method validation data for the GFAAS method for determination of ΣOT in potato and sugar beet matrices[a].

Commodity	MRID	Analyte	Fortification Level (ppm)[b]	Percent Recovery
sugar beets	42806101	TPTH	0.15	117, 106, 103, 105, 126, 117, 118
potatoes	42806101	TPTH	0.15	102, 108, 97, 112, 101, 107, 90
sugar beets	41556601 41556602 41785201 41785202 41785203 41785204	MPTH	0.015 0.06 0.31	113, 86, 109 68, 154, 86 85, 87, 88
		DPTH	0.015 0.06 0.31	191, 126, 112 64, 108, 77 88, 86, 85
		TPTH	0.015 0.06 0.31	128, 265, 168 76, 80, 82 81, 76, 71
potatoes	41556601 41556602 41785201 41785202 41785203 41785204	MPTH	0.015 0.031 0.31	126, 170, 165 96, 114, 0 90, 133, 100
		DPTH	0.015 0.031 0.31	97, 96, 120 123, 100, 78 115, 81, 133
		TPTH	0.015 0.031 0.31	127, 121, 93 122, 173, 0 108, 102, 127
Sugar beet processed commodities:				
refined sugar dehydrated pulp molasses	41785201	TPTH	0.06-0.2[c]	104, 132 129, 293 281, 222
Potato processed commodities:				
wet peel dry peel granule chips	41785202	TPTH	0.06 0.2 0.2 0.2	136, 106 148, 161 123, 104 69, 86

[a]Data for this Table were taken from the registrant's Tables 1, 2, 5, 6, 9, 10, 13, and 14 in MRID 42806101. [b]Fortification levels were recalculated by the reviewer and are expressed in terms of parent TPTH, rather than Sn. [c]Exact fortification levels were not provided by the registrant.

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Table 2. Method validation data for the GC/FPD method for determination of the separate phenyltin compounds, TPTH, DPTH, and MPTH, in potato and sugar beet matrices[a].

Commodity	MRID	Analyte	Fortification Level (ppm)[b]	Percent Recovery[c]
sugar beets	41556601	MPTH	0.02	42, 37, 54
	41556602		0.08	44, 61, 55
	41785201		0.38	53, 80, 75
	41785202	DPTH[e]	0.02	100, 128, 56
	41785203		0.07	66, 97, 102
	41785204		0.37	88, 78, 74
		TPTH[d]	0.015	122, 72, 108
			0.06	102, 63, 181
			0.30	80, 76, 95
potatoes	41556601	MPTH	0.02	21, 20, 22
	41556602		0.04	76, 84, 33
	41785201		0.38	44, 85, 75
	41785202	DPTH[e]	0.02	74, 68, 42
	41785203		0.04	127, 120, 142
	41785204		0.37	117, 86, 117
		TPTH[d]	0.015	99, 56, 92
			0.031	113, 94, 100
			0.30	97, 111, 125
Sugar beet processed commodities:				
refined sugar	41785201	TPTH[d]	0.06-0.2[e]	88, 69
dehydrated pulp				72, 72
molasses				37, 83
Potato processed commodities:				
wet peel	41785202	TPTH[d]	0.06	88, 62
dry peel			0.2	130, 122
granule			0.2	105, 133

[a]Data for this Table were taken from the registrant's Tables 7, 8, and 11-14 from MRID 42806101. [b]Fortification levels were recalculated by the reviewer and are expressed in terms of parent TPTH, rather than Sn. [c]DPTH residues are expressed as the sum of MPTH and DPTH. [d]TPTH residues are expressed as the sum of MPTH, DPTH, and TPTH. [e]Exact fortifications levels were not provided by the registrant.

CBRS Deficiency #3

The registrant must provide data supporting their claim that analysis of organotin compounds is independent of the counterions present, in order to support their use of phenyltin chloride compounds as standards.

Registrant Response

The registrant presented a discussion indicating that triphenyltin and the other organotin compounds form Lewis salts with anionic moieties (such as chloride or hydroxide anions) that are inherently ionic in nature. These complexes rapidly dissociate in water and equilibrate with the other counterions in the sample matrix. Therefore, the chemistry of anionic complexes of tri-, di-, and mono-phenyltin complexes are identical in a sample matrix. Any chemical reactions carried out upon the phenyltin moieties, such as chelation-extraction and Grignard derivatization, are independent of the counterions present.

CBRS Conclusion

This deficiency has been resolved.

CBRS Deficiency #4

The data from the registrant's determination of phenyltin degradation rates must be submitted, and data quantifying the rate of breakdown to inorganic tin should be included.

Registrant Response

The registrant stated that the stability of the phenyltin compounds per se were not determined, and that the rate of degradation was not discussed in the original submission except to indicate that it happened during the period of sample preparation. The registrant explained that because the degradation appears to occur randomly and is matrix dependent, elucidation of the rate would be futile, and would require methodology which could completely differentiate between organic and inorganic Sn, which is currently unavailable.

CBRS Conclusion

This deficiency has been resolved.

CBRS Deficiency #5

The registrant must clarify the discrepancy concerning the stability of TTPTH (tetraphenyltin) during the extraction procedure.

Registrant Response

The registrant stated that an editorial error was made, which inadvertently included TTPTH in a statement regarding the stability of TPTH. The corrected sentence should read - 'The MDL for Triphenyltin (TPTH) is not quantified due to the unstable nature of this compound in the extraction procedure. The TPTH MDL is calculated as the sum of DPTH, MPTH, and TPTH.'

CBRS Conclusion

This deficiency has been resolved.

CBRS Deficiency #6

The contribution of inorganic tin to the total organotin analysis needs to be quantified in order to more accurately determine total phenyltin and to resolve the discrepancies between ΣOT from GFAAS analysis and the sum of phenyltins from GLC analysis.

Registrant Response

The registrant stated that the methodology to differentiate between organic and inorganic Sn is not available.

CBRS Conclusion

This deficiency has been resolved.

CBRS Deficiency #7

The data requirements may necessitate modifications to the method. If the registrant wishes to submit this GFAAS/GLC methodology for enforcement use, in addition to the data specified above, the method must be modified so that the tripropyl tin internal standard is derivatized separately from the TPTH residues and is added to the sample just prior to injection into the GLC. Complete descriptions and appropriate validation data must be submitted for modified methods. In addition, all data must be reported as TPTH equivalents.

Registrant Response

The registrant stated that the inclusion of the internal standard with the sample prior to derivatization is necessary to account for variability in derivatization efficiency between samples.

CBRS Conclusion

The inclusion of an internal standard in an enforcement method to account for variability in derivatization efficiency is not acceptable. According to the Residue Chemistry Guidelines, the registrant must develop an enforcement method that does not require this type of an internal standard for quantifying residues.

The registrant has not addressed the need to express the residue data in terms of parent TPTH. Method recovery data and the magnitude of the residue data reviewed in the TPTH Update were expressed in terms of Sn. In order to properly assess the tolerances for residues of TPTH in or on potatoes and sugar beets, all residue data used to support the established tolerances must be converted to TPTH equivalents.

CBRS Deficiency #8

The registrant must submit methodology for enforcement of tolerances for residues of TPTH, DPTH, and MPTH in meat, milk, poultry, and eggs. The method(s) should include a base hydrolysis step to release conjugated residues. Alternatively, the registrant must provide data indicating that base hydrolysis is unnecessary for adequate recovery of the total toxic residue. A complete description of the method(s) and appropriate validation data must be submitted.

Registrant Response

The registrant stated that enforcement methods for meat, milk, poultry, and eggs were not developed due to the sugar beet top feeding restriction. The registrant has committed to perform the necessary sugar beet field trials, and will develop the methodology if TPTH residues are found to exist on the sugar beet foliage.

CBRS Conclusion

This deficiency remains outstanding, pending submission and review of the requested data.

CBRS Deficiency #9

The proposed tolerance enforcement methodology must undergo successful confirmatory trials conducted by an independent laboratory. Results of at least one set of samples per commodity (a total of six samples, including two control samples, two control samples fortified at the tolerance level, and two control samples fortified at 2-5 times the tolerance level) must be submitted. No more than three sets of samples per commodity may be tested to achieve successful recovery rates of 70-120% with negligible interference compared to the established tolerances. For additional details of data requirements, refer to PR Notice 88-5, Tolerance Enforcement Methods-Independent Laboratory Confirmation by Petitioner.

Registrant Response

The registrant stated that enforcement methodology is on file.

CBRS Conclusion

The registrant provided no MRID or study number for the referenced method. The colorimetric methods currently listed in PAM, Vol. II determine TPTH per se, and none of these methods are adequate to enforce the proposed revised tolerance. Although current enforcement methodology adequately determines TPTH residues according to the current tolerance definition, new enforcement methodology must be developed and undergo successful confirmatory trials conducted by an independent laboratory to support the tolerance upon revision to include TPTH and its degradates DPTH and MPTH. This deficiency remains outstanding, pending submission and review of the required data.

CBRS Deficiency #10

Representative samples from plant and animal metabolism studies must be analyzed using proposed enforcement methodology in order to ascertain that these methods are capable of recovering all residues of concern. If analysis of samples from previously accepted metabolism studies is impractical, the registrant must provide data from other sources to demonstrate adequate recovery of the total toxic residue.

Registrant Response

The registrant stated that these data will be generated.

CBRS Conclusion

This deficiency remains outstanding, pending submission and review of the requested data.

CBRS Deficiency #11

Storage stability data are required in support of all required residue studies, reflecting the actual storage conditions and intervals for samples used to generate the residue data. All information relevant to fortification of samples must be provided. All samples must be fortified with TPTH and its di- and monophenyltin metabolites. If the registrant wishes to use the data from the studies submitted in MRIDs 41556601, 41556602, 41785201 and 41785202, to fulfill storage stability data requirements, an adequate explanation for the low zero day recoveries must be provided. Storage stability data must be collected using adequate analytical methodology. Data on the storage stability of TPTH, its di- and monophenyltin metabolites and of tetraphenyltin in sugar beet and potato processed commodities are required.

Registrant Response

The registrant stated that stability data for TPTH in potatoes, sugar beets, and refined sugar and molasses for the maximum period for which field residue samples were held in frozen storage has been submitted as MRID 42564801, and that the data indicate that there is no loss of analyte due to extended storage periods.

The registrant concluded that no further information would be gained by fortification with the DPTH or MPTH metabolites, because TPTH and DPTH degrade unpredictably into DPTH and MPTH, respectively, in the presence of homogenized potato and sugar beet matrices, and MPTH degrades similarly into inorganic tin.

CBRS Conclusion

The storage stability data (1992; MRID 42564801) cited by the registrant have been reviewed by CBRS (No. 11004, L. Cheng, 3/11/93). CBRS deferred conclusions pending submission of representative chromatograms for calibration curves, standards, and treated and untreated samples. This deficiency remains outstanding.

CBRS Deficiency #12

Data on the storage stability of TPTH residues of concern in or on sugar beet tops are required.

Registrant Response

The registrant stated that these data will be generated in association with the sugar beet field trials to be conducted in 1993.

CBRS Conclusion

This deficiency remains outstanding, pending submission and review of the requested data.

CBRS Deficiency #13

Data are still required depicting the storage stability of TPTH and its di- and monophenyltin metabolites in meat, milk, poultry, and eggs.

Registrant Response

The registrant stated that these data will be generated in association with the residue determination in meat, milk, poultry, and eggs if residues are found to exist in the sugar beet tops.

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CBRS Conclusion

This deficiency remains outstanding, pending submission and review of the requested data.

CBRS Deficiency #14

Carrot data are required from tests conducted in WA or OR. A representative FlC formulation must be applied at the maximum label rate and the number of applications must reflect the maximum permitted on the label. Samples must be harvested at a posttreatment interval that corresponds to the PHI on the label.

Registrant Response

The registrant stated that carrots were dropped from the label prior to the TPTH Update, and that no additional data to support a tolerance on carrots will be generated.

CBRS Conclusion

The example label included in the submission listed no uses for TPTH on carrots. This deficiency has been resolved.

CBRS Deficiency #15

The registrant must amend product labels to specify a PHI and a maximum seasonal application rate that is supported by the residue data. The available data indicate a PHI of 21 days and a maximum seasonal application rate of 0.75 lb ai/A is appropriate for potatoes and sugar beets. If the registrant elects to propose a different PHI or maximum seasonal rate, appropriate supporting residue data must be submitted.

Registrant Response

The registrant stated that the reviewed data was consistent with the recommended PHI's and use rates on the label submitted by the registrant prior to the Residue Chemistry Reregistration Standard Update, and referenced the current product label submitted in the Response.

CBRS Conclusion

The product label included in this submission currently lists a 21-day PHI and a maximum seasonal application rate of 0.75 lb ai/A for potatoes and sugar beets. This deficiency has been resolved.

CBRS Deficiency #16

A mean recovery value of 85.5% was reported for fortified potato samples analyzed concurrently with treated samples. We note that this same recovery value was reported in the sugar beet study. The registrant should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed.

Registrant Response

The registrant stated that both sugar beets and potatoes were analyzed in some of the analytical sample sets, and has submitted revised data tables including the concurrent method recovery data for individual samples.

CBRS Conclusion

The concurrent recovery value of 85.5% reported in the original Tables was an average of several recovery values taken from both potato and sugar beet RACs. In the current submission, the registrant submitted data for individual recoveries; these data are summarized in Table 3. Concurrent recovery data indicated that both the GFAAS and GC/FPD methods were adequate for sugar beet and marginal for potatoes. Recovery data for the sugar beet and potato processed commodities are inadequate since the concurrent method recoveries were generated at 3.1 ppm, which is higher than the residues found in refined sugar, molasses and potato granules. Concurrent method recoveries generated at levels comparable to the residue levels found in refined sugar, molasses and potato granules are needed.

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Table 3. Concurrent method recoveries for determinations of ΣOT and individual phenyltin compounds in potato and sugar beet matrices[a].

Commodity	MRID	Method	Analyte	Fortification Level (ppm)[b]	Percent Recovery
potatoes	41556601	GFAAS	DPTH	0.31	87
	41556602 41785202		TPTH	0.06	233, 89, 39
	41785202		TPTH	0.12	97, 74
sugar beets	41556601 41556602 41785201 41785202	GFAAS	TPTH	0.06	113, 88, 121
potatoes	41556601 41556602 41785202	GC/FPD	DPTH[c] TPTH[d]	0.31 0.06	<5, <5 76, 53, <5, <5, 65, 80
sugar beets	41556601 41556602 41785201 41785202	GC/FPD	TPTH[d]	0.06	78, 106
Potato processed commodities:					
potato, unwashed	42806101	GFAAS	TPTH	3.1	65
potato, washed					99
potato, peeled					83
granules					80
wet peel					79
dried peel					93
potato, unwashed	41785204	GC/FPD	TPTH[d]	3.1	45
potato, washed					100
potato, peeled					116
granules					84
wet peel					24
dried peel					24
Sugar beet processed commodities:					
dehydrated pulp	41785203	GFAAS	TPTH	3.1	50
molasses					93
refined sugar					107

[a]Data for this Table were taken from the registrant's Tables 16, 21, 24, and 27 from MRID 42806101. [b]Fortification levels were recalculated by the reviewer and are expressed in terms of parent TPTH, rather than Sn. [c]DPTH residues are expressed as the sum of MPTH and DPTH. [d]TPTH residues are expressed as the sum of MPTH, DPTH, and TPTH.

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CBRS Deficiency #17

Data are required depicting residues of TPTH and its metabolites, di- and monophenyltin hydroxide (or oxides) in or on sugar beets harvested 21 days following the last of three foliar applications with a representative WP or FlC formulation at 0.25 lb ai/A/application. Samples must be analyzed using an acceptable, validated analytical method. Tests must be conducted in CA as previously requested by the Agency.

Registrant Response

The registrant stated that field tests were conducted using PHIs and application rates specified on the current label, and that TPTH has not, and will not, be registered or sold in CA. The registrant concluded that there is therefore no need for studies to be conducted in CA.

CBRS Conclusion

The registrant must revise its product labels prohibiting the use of TPTH on sugar beets grown in CA (which accounted for 18% of the U.S. sugar beet production in 1989, Agricultural Statistics, 1991, p. 74) or submit data from CA depicting TPTH residues in or on sugar beet tops and roots harvested 21 days following the last of three foliar applications each at 0.25 lb ai/A with a representative WP or FlC formulation. This deficiency remains outstanding, pending submission and review of the revised labels or the requested data.

CBRS Deficiency #18

The registrant must amend all pertinent product labels to specify a PHI and a maximum seasonal application equivalent to that reflected in the data used to support the tolerance. The available data indicate that a PHI of 21 days and a maximum seasonal application rate of 0.75 lb ai/A would be appropriate. Otherwise, additional data are required.

Registrant Response

The registrant stated that product labels have been changed, referencing the current product label included in the Response.

CBRS Conclusion

This deficiency has been resolved.

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CBRS Deficiency #19

Additional data are needed from the studies submitted in MRIDs 41785201 and 41785203. Chromatograms and/or raw data are needed to estimate total phenyltin residues and determine whether or not residues concentrate. Recovery data, including fortification levels in ppm should also be provided.

Registrant Response

The registrant provided representative chromatograms. The registrant stated that sufficient data have been presented to determine whether or not residues concentrate in potatoes and sugar beets. The supporting data tables presented in the original submission were also included in the current submission.

CBRS Conclusion

This deficiency has been resolved.

CBRS Deficiency #20

The Agency has determined that a feeding restriction for sugar beets is impractical. The registrant must submit data depicting TPTH residues of concern in or on sugar beet tops and propose a suitable tolerance. Tests must reflect the maximum application rate and the maximum number of applications per season permitted on the labels. Tests must be conducted in CA(18%), ID(16%), MI(10%), MN(22%), ND(11%), NE(5%), and WY(5%), states which collectively accounted for approximately 87% of U.S. sugar beet production in 1989 (Agricultural Statistics, 1991, p. 74). All pertinent product labels must be amended to delete grazing/feeding restrictions for sugar beet tops.

Registrant Response

The registrant stated that a study will be conducted in 1993 with field trials in the suggested states to satisfy the data requirements, but that trials in California will not be conducted since the product will not be registered or sold in that state. Feeding and grazing restrictions will be removed from the product label.

CBRS Conclusion

The registrant must remove the grazing/feeding restriction for sugar beet tops from the labels and amend product labels to restrict all product usage in California. This deficiency remains outstanding, pending submission and review of the required data.

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CBRS Deficiency #21

Peanut field trials from TX are required. In addition, peanut hulls must be analyzed since they are not under the control of the grower. The label must state a maximum number of applications of TPTH per season. Alternatively, residue data reflecting the maximum theoretical number of applications may be submitted.

Registrant Response

The registrant stated that it is no longer supporting the tolerance for TPTH on peanuts and that peanut uses have been deleted from TPTH labels.

CBRS Conclusion

This deficiency has been resolved.

CBRS Deficiency #22

No data from a processing study with peanuts have been submitted. Data are required depicting the potential for residue concentration in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

Registrant Response

The registrant stated that it is no longer supporting the tolerance for TPTH on peanuts and that peanut uses have been deleted from TPTH labels.

CBRS Conclusion

This deficiency has been resolved.

References

Citations for the MRID documents referenced in this review are presented below. Submissions reviewed in this document are indicated by shaded type.

42806101 Silvoy, J. (1990) Triphenyltin Hydroxide (TPTH): Residue Chemistry: Lab Project Number: TPTH REREGISTRATION STANDARD UPDATE. Unpublished study prepared UPDATE. Unpublished study prepared by Battelle Lab. 93 p.

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41556601 Sibuay, J; Guy, S. (1990) LV1169-01 (Triphenyltin Hydroxide): Raw Agricultural Commodity: Field Residue Study on Sugar beet in North Dakota, Minnesota, Idaho, Nebraska, Colorado and Michigan. Lab Project No. N-0535-01: N-0535-0102: 1714-89-01-08B-01. Unpublished study by Battelle Laboratories, Inc. 585 p.

41556602 Sibuay, J; Guy, S. (1990) LV1169-01 (Triphenyltin Hydroxide): Raw Agricultural Commodity: Field Residue Study on Potato in Maine, North Dakota, Washington, Idaho and Minnesota. Lab Project No.: N-0535-01: N-0535-02: 1714-89-169-01-08D-0. Unpublished study by Battelle Laboratories, Inc. 605 p.

41785201 Silvoy, J. (1990) LX1169-01 (TPTH): Processed Commodity Field Residue Study on Sugar beets in Idaho: Final Report: Lab Project No: N-0535-0101: N-0535-0103: 1714-89-169-01-08B-05. Unpublished study prepared by Battelle. 234 p.

41785202 Silvoy, J. (1990) LX1169-01 (TPTH): Processed Commodity Field Residue Study on Potatoes in Washington: Final Report: Lab Project No: N-0535-0101: N-0535-0103: 1714-89-169-01-08D-14. Unpublished study prepared by Battelle. 332 p.

42564801 Uhler, A.; Spellacy, A. (1992) Storage Stability Study of Triphenyltin in Potato and Sugar Beet Raw Agricultural Commodities and the Sugar Beet Processed Commodities Sugar and Molasses: Final Report: Lab Project Number: SD910032. Unpublished study prepared by Battelle Ocean Sciences. 39 p.

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